

REMARKS/ARGUMENTS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the above amendments and following remarks, which place the application into condition for allowance.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-33 are pending in this application. Claims 1-12 and 31-33 have been withdrawn from consideration by a previous amendment. Claims 13-30 are rejected in the Office Action mailed on August 21, 2009.

II. THE REJECTIONS UNDER 35 U.S.C. § 112

Page 2 of the Office Action rejects claim 21 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Office Action asserts that claim 21 is confusing because it recites that the face mask covers the upper part of the head and claim 13, from which claim 21 depends, allegedly recites that the mask covers the nose and mouth. Applicants respectfully traverse for at least the following reasons.

Claim 13 recites, *inter alia*:

A device comprising a facial mask accommodated to allow **unobstructed respiratory function of the nostrils and the mouth**, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad...(Emphasis added.)

Claim 21 recites:

The device according to claim 13, wherein the facial mask covers an upper part of a person's head.

Claim 13 recites that the respiratory function of the nostrils and mouth are unobstructed. Because the mask according to claim 13 allows **unobstructed respiratory function of the nostrils and the mouth**, and a covering of the nostrils or mouth would provide some obstruction, there is no indication in the claim that the nostrils and mouth are covered. Further, each embodiment of the invention as shown in the figures illustrates the nostrils and mouth as being uncovered.

Consequently, contrary to the assertion in the Office Action, there is no recitation, or even a suggestion, that any part of the mask covers the nose and mouth.

Claim 21, recites that the facial mask covers an upper part of a person's head. This is in no way conflicting with claim 13.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the § 112 rejection.

III THE REJECTIONS UNDER 35 U.S.C. § 103(a)

On page 4 of the Office Action, the Examiner rejects claims 13-14, 17-19, 21-26, and 30 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of GB 2088714 to Marinello ("Marinello"), U.S. Patents Nos. 2,262,711 to Ludwin ("Ludwin") and 6,748,949 to Smaldone ("Smaldone"). The rejections are traversed for at least the following reasons.

Claim 13 recites:

A device comprising a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth, **an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient**, wherein the device promotes the **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** of a person in need thereof. (Emphasis added.)

Marinello is directed to use oil of horseradish or oil of mustard dissolved in vegetable oil, the vegetable oil producing the unexpected result of attenuating the revulsive power of the oil. *Marinello*, page 2, lines 94-108. Marinello teaches that vegetable oil is necessary to prevent reddening of the skin, an acute burning sensation, and an abnormally large amount of blood flow to the site of such intensity that intolerable pain results if the revulsion is applied for more than a short time. *Id.*, page 2, lines 75-82. At least part of the medicinal composition (revulsive and vegetable oil mixture) applied reaches the blood vessels and provokes their enlargement and an increased blood flow. *Id.*, page 3, lines 32-33.

Applicants respectfully submit that the revulsive and vegetable oil composition disclosed in *Marinello* is not suitable for **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person** as required by claim 13. The vegetable oil, because of its characteristic density is not suitable to penetrate the skin pores to reach the bones and mucous membranes underlying the skin. As disclosed in *Marinello*, the reaction achieved by the composition is limited to the superficial blood vessels (*Marinello*, page 2, line 29) and deep blood vessels (*Id.*, page 2, line 114).

The Office Action points to page 5, lines 11-20 to suggest *Marinello* treats sinusitis. However, page 5, lines 20-26 indicates the advantages of *Marinello* are hyperemia and slow general tumefaction in the area. Both of these conditions are related to increased blood flow. There is no suggestion that the composition or method of *Marinello* is suitable for **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person** as required by claim 13.

On page 5, the Office Action concedes that *Marinello* fails to teach the use of a facial mask as presently claimed. Instead, Ludwin is relied upon for such a teaching. However,

Ludwin is directed to a nebulizer, which vaporizes medicaments to be applied in the form of a vapor into respiratory passages. The nebulizer of Ludwin delivers medicament in a manner completely different from that claimed. The application of medicament to the small pores of the tracts of the sinus tracts through vaporization is not the same as applying an active ingredient through the skin to underlying bone.

In the last paragraph on page 5, carrying over to page 6, the Office Action recognizes that Ludwin teaches a medical nebulizer comprising a face mask, medicament in a chamber, and pressure provided to vaporize the medicine, citing to column 1, lines 13-19 of Ludwin. However, the cited portion of the reference recites, "The invention is a mask...connected by a tube to a nebulizer, in which the medicament is contained..." There is no teaching of **an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient** as required by claim 13.

The Office Action recognizes Ludwin teaches a "pressure provided to vaporize the medicine." Ludwin is therefore an aerosol device, which is the principle of operation of a nebulizer. The treatment of sinusitis through aerosol is based on intranasal absorption of the active ingredient which has been nebulized in very small drops that must be delivered to the sinus through the nasal cavity.

Accordingly, Ludwin does not disclose a device that **promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes** as required by claim 13.

Furthermore, contrary to the assertion in the Office Action, there is no teaching of **an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said**

inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes as required by claim 13.

Page 6 of the Office Action concedes that Ludwin “does not explicitly teach that the face mask is unobstructive and covers the nose and mouth.” The Examiner asserts that Smaldone teaches a face mask for delivering pressurized drugs from a nebulizer, the face mask covering the nose and mouth of the wearer and has openings to release undesired amounts of the drug. The Examiner concludes that because there are openings, respiration functions of the nose and mouth are unobstructed. Applicants respectfully disagree.

Because Smaldone is directed to a face mask for a nebulizer, the reference contains the same deficiencies as discussed above for Ludwin. Smaldone describes in detail the operating principle behind nebulizers in general. See, for example, *Smaldone*, column 1, lines 24-43. Smaldone discloses that with a nebulizer, “the aerosol and the drug are breathed in through the mask and administered into the respiratory system of the patient as the patient inhales.” *Id.*, lines 25-28. Applicants respectfully submit that the holes in the mask of Smaldone do not change the principle of operation of a nebulizer.

Smaldone recites that in related art masks used for drug delivery in a nebulizer or a metered dose inhaler, when a patient wearing the face mask inhales, “a negative pressure is applied to the face mask reservoir and the aerosolized drug is inhaled and enters the respiratory system of the patient.” *Smaldone*, column 1, lines 40-43. Smaldone also recites that the inventive mask disclosed is of a similar construction as the related art face masks, with the one exception of a “vent 110 which serves to discharge aerosol.” *Smaldone*, column 7, lines 28-29 and 58-59. .

Accordingly, in order for the inhalation of the patient to create a negative pressure within the mask reservoir, some resistance to the inhalation must be created. Therefore, contrary to the Examiner's assertion, the mask taught by Smaldone does not provide for unobstructed respiration.

Beginning on page 6, the Office Action presents alleged findings in support of a case of prima facie obviousness. Applicants respectfully disagree with the findings, and submit that a prima facie case has not been made, for at least the following reasons.

The Office Action asserts that at the time of the present invention, it was known to treat sinusitis by administering a dressing impregnated with mustard oil to the skin overlying sinuses and using an inflatable elastic pad to squeeze the revulsive agent from the compress, as taught by Marinello.

As discussed above, Marinello discloses use of revulsive and vegetable oil composition to stimulate blood flow in tissue underlying the skin. *Marinello*, page 2, lines 94-115. There is no disclosure that the active ingredients are capable of penetration **through the skin to bones underlying mucous membranes in a sinus** as claimed. In fact, Applicants submit that the vegetable oil makes such a composition unsuitable for penetration of the skin.

On page 7, the Office Action asserts, "delivering medicaments to the sinuses using impregnated dressing and face mask using pressure force was known in the art at the time of the invention as taught by Ludwin." Applicants respectfully submit that the Office Action misconstrues the teaching of the reference.

As discussed above, Ludwin discloses a nebulizer. As described in column 1, lines 13-39 of Ludwin, air under pressure is supplied to the nebulizer, passing over the medicament to volatilize the medicament for application in the form of a vapor. The disclosed nebulizer provides

the active ingredient in aerosol form through the nasal cavity. There is no suggestion that the nebulizer disclosed by Ludwin **promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes** as required by claim 13. In fact, delivery of medicament in a manner other than through the nasal passages would be contrary to the function of a nebulizer.

On page 7, the Office Action asserts it would have been obvious to use the face mask of Ludwin with the invention of Marinello. However, use of an aerosol face mask for a nebulizer on the mask of Marinello would change the principle of operation of Marinello. As explained at M.P.E.P. §2143.01:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

Marinello relies on the vegetable oil composition to allow the solution to be maintained on the body for a longer period of time, thus allowing the revulsive to enter the pores of the skin to cause reactions in the blood vessels in the region. *Marinello*, page 2, lines 103-115. Ludwin discloses a means for volatilizing the medicament so that it may be applied in the form of a vapor (*Ludwin*, column 1, lines 40-43) for aerosol application of a medicament to the nasal passages. Accordingly, because modifying Marinello to include the mask of Ludwin would change the principle of operation of Marinello, the Office Action has failed to make a *prima facie* case of obviousness.

Smaldone discloses a nebulizer mask as discussed above. Modifying Marinello with the nebulizer mask Smaldone is not *prima facie* obvious for the same or similar reasons as discussed above with regard to Ludwin.

For at least the foregoing reasons, it is believed that revised independent claim 13 patentably distinguish over the relied upon portions of Ludwin, Marinello and Smaldone, either alone or in combination, and is therefore allowable. Independent claim 25 is similar or somewhat similar in scope to revised independent claim 13 and is therefore allowable for similar or somewhat similar reasons to those for claim 13. Further, claims 14-24, which depend from claim 13, and claims 26-30 which depend from claim 25, are allowable as well.

The Examiner has made of record, but not applied, several documents. The Applicants appreciate the Examiner's implicit finding that these documents, whether considered alone or in combination with others, do not render the claims of the present application unpatentable.

Statements appearing above with respect to the disclosures in the cited references represent the present opinions of the Applicants' undersigned attorney and, in the event that the Examiner disagrees with any such opinions, it is respectfully requested that the Examiner specifically indicate those portions of the respective reference providing the basis for a contrary view.


CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are patentable over the prior art, and an early and favorable consideration thereof is solicited.

Please charge any fees incurred by reason of this response and not paid herewith to Deposit Account No. 50-0320.

Respectfully submitted,
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